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Attorneys for Plaintiffs, MARILE ARAGON and RODNEY ARAGON

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

IN RE DEPUY ORTHOPAEDICS, INC.] PINNACLE HIP IMPLANT PRODUCTS] LIABILITY LITIGATION]	MDL Docket No.: 3:11-md-02244;K (Related Case: 3:15-cv-0040-K) *Honorable Ed Kinkeade*
This document relates to:]	CASE NO. 3:18-cv-0544-K
MARILE ARAGON, RODNEY ARAGON,] Plaintiffs,] vs.] DEPUY ORTHOPAEDICS, INC., An Indiana Corporation; DEPUY INC., A Delaware Corporation; JOHNSON & JOHNSON, A New Jersey Corporation; JOHNSON & JOHNSON SERVICES, INC., A Delaware Corporation; JOHNSON & JOHNSON INTERNATIONAL, INC., A Delaware Corporation, inclusive,] Defendants.]	FIRST AMENDED COMPLAINT FOR DAMAGES

Comes now Plaintiffs MARILE ARAGON and RODNEY ARAGON, pursuant to this Court's SCHEDULING ORDER (Document 30), and allege for a First Amended Complaint as follows:

I. PARTIES

1. Plaintiff MARILE ARAGON, an individual, is a resident of Orange County, State of California. Plaintiff MARILE ARAGON brings this action for personal injury damages as a result of a defective hip prosthesis which was placed into the stream of commerce in, without limitation, the County of Orange, in the State of California, by one or more named defendants.

2. Plaintiff RODNEY ARAGON, an individual, is a resident of Orange County, State of California. At all times relevant, Plaintiffs MARILE ARAGON and RODNEY ARAGON have long been lawfully wedded as Husband and Wife. Plaintiff RODNEY ARAGON, as Plaintiff MARILE ARAGON's spouse, brings his own claim for Loss of Consortium damages.

3. Defendant DEPUY ORTHOPAEDICS, INC. is a corporation organized and existing under the laws of the State of Indiana, with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY ORTHOPAEDICS, INC. is a wholly owned subsidiary of defendant Johnson & Johnson, or a wholly owned subsidiary of defendant DePuy, Inc. At all times relevant to this action, defendant DEPUY ORTHOPAEDICS, INC. was authorized to, and did, conduct business throughout the State of California, including without limitation in the County of Orange, State of California.

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4. Defendant DEPUY, INC. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DEPUY, INC. is a wholly owned subsidiary of defendant Johnson & Johnson, Inc. At all times relevant to this action, defendant DEPUY, INC. was authorized to, and did, conduct business throughout the State of California, including without limitation in the County of Orange, State of California.

5. Defendant JOHNSON & JOHNSON SERVICES, INC. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON SERVICES, INC. is a subsidiary of defendant Johnson & Johnson. At all times relevant to this action, defendant JOHNSON & JOHNSON SERVICES, INC., was authorized to, and did, conduct business throughout the State of California, including without limitation in the County of Orange, State of California.

6. Defendant JOHNSON & JOHNSON INTERNATIONAL, INC. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON INTERNATIONAL, INC. is a subsidiary of defendant Johnson & Johnson. At all times relevant to this action, defendant JOHNSON & JOHNSON INTERNATIONAL, INC. was authorized to, and did, conduct business throughout the State of California, including without limitation in the County of Orange, State of

California.

7. Defendant JOHNSON & JOHNSON is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant JOHNSON & JOHNSON is the parent company of defendants Johnson & Johnson Services, Inc., Johnson & Johnson International, Inc., DePuy, Inc., and DePuy Orthopaedics, Inc. At all times relevant to this action, defendant JOHNSON & JOHNSON was authorized to, and did, conduct business throughout the State of California, including without limitation in the County of Orange, State of California.

8. Defendants JOHNSON & JOHNSON, JOHNSON & JOHNSON SERVICES, INC., JOHNSON & JOHNSON INTERNATIONAL, INC., DEPUY, INC., AND DEPUY ORTHOPAEDICS, INC. (hereinafter collectively denominated solely for convenience as "DePuy") jointly developed, manufactured, advertised, promoted, marketed, sold, and/or distributed medical systems generally known as DePuy "ASR" and "Pinnacle" hip prostheses systems throughout the United States, and throughout the State of California, including without limitation in the County of Orange, State of California.

9. The DePuy ASR hip prostheses system has been recalled, and that the Pinnacle hip prostheses system has been discontinued, and may be subject to a recall. The DePuy ASR and Pinnacle hip prostheses systems are similarly defective and have caused injury to numerous persons, as a result of such defects, and the DePuy Pinnacle hip prostheses system has caused injury to plaintiffs.

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10. At all times and places relevant, defendants, and each of them, were the agents, ostensible agents, co-conspirators, servants, employees, partners, joint venturers, affiliates, franchisees, and/or alter egos of the remaining defendants, and each of them, and that each of them were at all times and places relevant herein were acting in concert and within the purpose and scope of such conspiracy, service, agency, ostensible agency, employment, partnership, joint venture, affiliation, and/or franchise.

II. JURISDICTION AND VENUE

11. While a part of the MDL Proceeding captioned above, the Northern District of California has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because Plaintiffs and Defendants are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs. Jurisdiction is further proper because the defective product which injured plaintiffs was placed into the stream of commerce by defendants in the County of Orange, because one or more of the named defendants committed acts causing harm to Plaintiffs in the County of Orange, because one or more of the named defendants committed acts knowing of the harm and damages that would be caused in the State of California, thereby purposefully availing themselves of the laws of this state, and in the County of Orange. Additionally, California has a greater interest in the acts alleged herein than any other state, and the application of state law other than California state law would be contrary to a fundamental policy of this state, which has a greater interest in the determination of

the matters alleged. It would be unreasonable to require trial of this action anywhere other than in California.

12. Venue is proper pursuant to 28 U.S.C. § 1391(a), (b), and (c), and Civil Local Rule 3-2 ©.) Venue is appropriate herein, because the claims alleged in this complaint arise from and are related to the defective product which was placed in the stream of commerce throughout the United States, throughout the State of California, including without limitation in the County of Orange, and because a substantial part of the events or omissions which give rise to the claim occurred in the County of Orange, and because Defendants committed acts.

III. MEDICAL FACTS COMMON TO ALL CLAIMS FOR RELIEF

Plaintiff's Original Hip Implant Surgery

13. During the year of 1998, Plaintiff MARILE ARAGON, suffering from what was identified by Pre-Operative and Post-Operative Diagnoses as Right hip arthritis, underwent a right total hip replacement ("THR") surgical procedure implanting a prosthetic medical system.

14. The implanted prosthesis developed an a septic loosening due to polyethylene wear and osteolysis that required a total hip revision in 2012. Dr. Anntol Podalsky performed that surgery inserting a DePuy hop prothesis.

15. As a result of the design, manufacture and composition of that original hip prosthesis medical System, and its accompanying warnings and instructions (or lack thereof), certain components thereof eventually failed which caused severe pain, and immediate disability as alleged. At some point after the original hip

prosthesis implant surgery, but unbeknownst to plaintiff, the DePuy hip prosthesis stem fractured.

Plaintiff's Second Hip Implant Surgery

16. On or about September 21, 2017, in the late evening, plaintiff MARILE ARAGON presented to Anatol Podalsky, M.D., after experiencing severe and excruciating right hip and groin pain for four to five months.

17. As a result, Dr. Podalsky conducted a third revision surgery on September 23, 2017 reinserting a DePuy prothesis described as "long stem size 15, head 36+8.5 delta ceramic".

18. Medical records reveal that plaintiff's prosthesis had suffered a fracture of the stem in its mid portion, angulation and loosening of the proximal portion of the left femur.

19. As a direct and legal consequence of the medical system failure alleged above and the defects as described herein, plaintiff was forced to undergo and recover from an original, intermediate, and final hip implant surgeries, and will likely be required to undergo future hip revision surgery, suffered substantial pain and suffering, live with debilitating pain, impaired ability to walk, and numerous other medical ailments not otherwise apparent. As a further proximate result of the medical system failure alleged above and the defects as described herein, plaintiff's hospitalization was complicated by rental insufficiency.

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IV. PRODUCT FACTS COMMON TO ALL CLAIMS FOR RELIEF

The Defective Hip Implant System Originally Implanted In Plaintiff

20. This product liability lawsuit stems from the failure of that certain medical system known as the DePuy prosthesis inserted into plaintiff MARILE ARAGON's left hip by Dr. Anatol Podalsky.

21. The Pinnacle System prosthetic hip implant System is a direct predecessor to the DePuy ASR System, which was also a prosthetic hip implant, albeit one which defendants finally were forced to recall (on or about August 24, 2010) due to high failure rates and severe complications, which defendants concealed despite their awareness of same.

22. The Pinnacle System suffers from similar design or manufacturing defects as the now-recalled ASR System, yet Defendants continued to sell these implants without any warnings despite significant System failures that have been reported to the defendants. Plaintiffs allege that defendants have now discontinued the Pinnacle System.

23. Defendants manufactured the Pinnacle Acetabular Cup System ("Pinnacle System"), and launched it in 2001. The Pinnacle System was designed, developed, and sold for human hip joints damaged or deceased due to fracture, osteoarthritis, rheumatoid arthritis, and avascular necrosis. The Pinnacle System is designed to be fastened to human bone with surgical screws. The Pinnacle System was designed and sold to provide pain relief and consistent and smooth range of motion.

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24. Defendants marketed the Pinnacle System as having significant advantages over other hip replacement systems. Defendant marketed and described the Pinnacle System as "uniquely designed to meet the demands of active patients like you - and help reduce pain," and, for example, advertised it with pictures of a young woman trying on sneakers in an athletic shoe store.

25. Defendants advertised the Pinnacle System as a superior System featuring TrueGlide Technology, allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion."

26. Defendants also advertise and sold the Pinnacle System as the best surgical option that "recreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

27. On information and belief Plaintiff alleges that Defendants sold about 150,000 Pinnacle Systems. Defendants have stated in promotional materials -that "99% of Pinnacle Hip components are still in use today.

28. However, and on information and belief, Plaintiff alleges that over 1,300 adverse reports have been submitted to the U. S. Food and Drug Administration (FDA) regarding failures or complications of the Pinnacle System.

29. On information .and belief, Plaintiff alleges that Defendant are and were aware that the use of the Pinnacle System may result in metallosis, biologic toxicity, and a high failure rate.

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30. Plaintiff further alleges that use of the Pinnacle System results in unsafe release of toxic metal ions into hip implant recipients' tissue and bloodstream. Plaintiff further alleges that Defendants are and have long been aware that metal particles from the Pinnacle System results in metallosis, tissue death, bone erosion, and development of tumors.

31. On information and belief, Plaintiff alleges that particulate debris from the Pinnacle System causes severe inflammation, severe pain, tissue and bone loss, and other related disease processes.

32. Plaintiff further alleges that Defendants are and were aware that certain Pinnacle System recipients have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

33. Plaintiffs allege that the ASR System and the Pinnacle System had high rates of loosening, failure, design defects, manufacturing defects, and dangerous metal debris release, which caused patients to develop complications to the point where they had to undergo "revision" surgeries. A revision surgery is a painful procedure during which some or all of the parts of the previously implanted hip prosthesis are surgically extracted from the patient's body and new prosthetic parts implanted. The revision procedure may also involve the removal of large amounts of necrotic tissue and bone due to the defective System. Defects with the System, and other acts and omissions of defendants, known or unknown, proximately caused the injuries and damages of which plaintiffs complain. Plaintiff underwent a revision surgery.

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34. Plaintiff MARILE ARAGON was implanted with the Pinnacle System during the year 1998. After implantation in her body, that System failed as alleged hereinabove.

35. Prior the date of plaintiff's original hip implant surgery, defendants knew that the original ASR System: was "too challenging" from a surgical perspective, that the ASR and Pinnacle Systems shared abnormally high risks of early failure; generated unusual and dangerous levels of toxic metal debris in many patients' bodies; left patients more susceptible to infection; had defects that caused a destructive process of bone and tissue; and caused other complications. Despite actual and constructive notice of such problems and defects, defendants continued to market, sell, promote, and defend the defective ASR and Pinnacle System for years. Defendants did not warn doctors or patients of unacceptable risks presented by their products. Instead, defendants concealed these problems, falsely claimed these Systems were safe, while knowing that they were not. As a result, plaintiff was implanted with a defective System as alleged hereinabove, developed painful and dangerous complications, had to undergo three revision surgeries and related medical procedures, will likely have to undergo one or more surgeries, and will have lifelong residual problems. The following allegations outline the presently known issues as to these similarly defective medical Systems.

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The Defective DePuy ASR System

36. The ASR System is designed so that the natural hip joint is replaced with metallic components that articulate against each other. A System designed to have direct metallic articulation, without any sort of buffer between ball and socket, is known within the industry as "metal-on-metal" system. The ASR System is a metal-on-metal System.

37. In an ASR System total hip replacement surgery, three components are implanted: (1) a femoral stem; (2) a ball-shaped metal femoral head that connects to the top of the femoral stem; and (3) an acetabular cup. The ASR's metallic components are designed to articulate each other and function like a natural hip once the healing process is complete.

38. The ASR acetabular cup is different from other existing hip prostheses in several ways, including without limitation that the walls of the ASR cup are thinner than competing cups, and are more susceptible to deformation on placement; the designed clearance between the ASR cup and ball is the smallest in the industry and insufficient; the ASR cup has no means of immediate fixation; the outside shell of the ASR cup lacks reliable boney ingrowth compounds and materials; the ASR cup is sub-hemispherical and shallower than other Systems; the ASR cup is double-heat treated.

39. On information and belief, Plaintiff alleges that the ASR and the Pinnacle System were designed by the same physicians: Dr. Thomas Schmalzried, M.D., and Thomas Parker Vail, M.D. Defendants began selling the ASR System in European and other markets in 2003.

On or about August 5, 2005, defendants began to market the ASR System in the United States.

40. In or about 2006, DePuy distributed a glossy 24-page brochure to orthopedic surgeons all over the United States. The purpose of that brochure was to encourage orthopedic surgeons to implant the ASR System into their patients. Head shot photographs of Dr. Vail and Dr. Schmalzried appeared on the second page of the brochure with the following text: "The ASRTM XL metal-on-metal articulation product rationale has been developed in collaboration with Thomas Schmalzried, M.D. [and] Thomas Parker Vail, M.D."

41. Manufacturers of other metal-on-metal prosthetic hip Systems carefully screened, selected, and trained those orthopedic surgeons who would be authorized to use their Systems. The other manufacturers' training focused on, among other things, how to properly implant the Systems. Defendant-Manufacturers, however, did not screen, select or train surgeons on how to implant the ASR System. Instead, they aggressively marketed, promoted and encouraged orthopedic surgeons in the United States to adopt and use the ASR System, giving these surgeons little or no training or guidance on how to implant the System.

42. Beginning within two years of its introduction in 2003, defendants started receiving warnings that the ASR System was defective and failing with catastrophic consequences for patients. When an artificial hip fails, it must be surgically removed and, if possible, replaced with new implant components (i.e., revision surgery.) Defendants were warned not only that the ASR System was failing at an unacceptably high rate, but that some ASR System

patients were having serious complications including massive tissue and bone death. Defendants actively concealed this information and instead misled orthopedic surgeons, the medical community, and others.

43. Plaintiffs allege the following with regard to Dr. Vail's and Dr. Schmalzried's ongoing involvement with the DePuy ASR System: Dr. Vail and/or Dr. Schmalzried met with orthopedic surgeons who had implanted the ASR System and who had concerns about the System, including without limitation, that the ASR System did not perform as expected, failed frequently, generated excessive and dangerous levels of metal debris, and had disastrous complications and side effects in some patients. At some or all of these meetings, representatives of DePuy were also present; Dr. Vail, Dr. Schmalzried and the DePuy representatives assured the orthopedic surgeons during these meetings that the ASR System was safe, was the best product on the market, had an excellent track record, and a low and acceptable failure rate; Dr. Vail, Dr. Schmalzried, and the DePuy representatives vigorously defended the ASR System during these meetings, stating or implying that any problem with the ASR System in a particular-patient was attributable to flawed surgical technique; Dr. Vail, Dr. Schmalzried, and the DePuy representatives made such statements even after they became aware of numerous and serious complications with the ASR System; Dr. Vail, Dr. Schmalzried, and the DePuy representatives did not reveal, but concealed, their knowledge of numerous and serious complications during their meetings with orthopedic surgeons. The Defective DePuy Pinnacle System

44. Like the ASR System, the Pinnacle System implanted in Plaintiff is also a metal-on-metal System, wherein the ball-shaped metal femoral head was designed to articulate directly against an acetabular cup with a metal liner.

45. The Pinnacle System suffers from the same or very similar design and/or manufacturing defects as does the recalled ASR System. While the exact nature of the common defect awaits discovery, Plaintiffs allege that both ASR and Pinnacle prostheses suffer from one or more similar design or manufacturing defects that cause excessive amounts of cobalt and chromium to wear and chip from the surface of the acetabular liner, or from the femoral head, or from the taper area between the femoral component and femoral ball. These cobalt and chromium fragments prompt the body to react by rejecting the debris as an invading foreign body. This rejection typically manifests with symptoms of pain, looseness, dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues, muscle, ligaments, and bone to die.

46. The Pinnacle System was developed for the purpose of reconstructing diseased human hip joints from conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), fracture, and other degenerative conditions. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

47. The Pinnacle System is made up of four components: the metal femoral stem is inserted inside the femur bone, the metal femoral head (or ball) connects to the top of the stem and then makes contact with a liner that is attached to the interior portion of the metal acetabulum cup (socket). The acetabulum cup is comprised of titanium metal. Either a plastic, ceramic, or cobalt-chromium metal liner is then placed on the inside of the acetabulum cup. The metal femoral head rotates within the plastic, ceramic, or metal liner, depending on which liner the surgeon selects based on the patient's needs. The Pinnacle System is a "metal-on-metal" System due to the fact that both articulating surfaces-the femoral head (ball) and acetabulum liner (socket)-are comprised of cobalt-chromium metal.

48. The design of the Pinnacle System was not sufficiently tested by the defendants, and it was never approved by the FDA as being safe or effective for the product's intended purpose. Defendants did not seek premarket approval from the FDA, so it made no finding that the Pinnacle System was safe or effective

49. The Pinnacle System is a Class III medical System. Class III Systems are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

50. The Medical System Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), require Class III medical Systems, including the Pinnacle System, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of

that investigation to the FDA.

51. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the System's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the System's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such System; samples or System components required by the FDA; and a specimen of the proposed labeling.

52. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical System is safe and effective and must weigh any probable benefit to health from the use of the System against any probable risk of injury or illness from such use.

53. A medical System on the market prior to the effective date of the MDA (a so called "grandfathered" system), was not required to undergo premarket approval. In addition, a medical System marketed after the MDA's effective date may bypass the rigorous premarket approval process if the System is "substantially equivalent" to a "grandfathered" pre-MDA System (i.e., a System approved prior to May 28, 1976.) This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a System at least 90 days prior to the

System's introduction on the market, and to explain the System's substantial equivalence to a pre-MDA predicate System. The FDA may then approve the new System for sale in the United States.

54. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, the Pinnacle System metal-on-metal total hip replacement system was certified to be sold on the basis of Defendants' claim that, under section 510(k) of the MDA, it was "substantially equivalent" to an older metal-on-metal hip implant System that Defendants sold and implanted prior to the enactment of the MDA in 1976.

55. As such, under the 510(k) process, Defendants were able to market the Pinnacle System with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

56. Together with the other defendants, Schmalzried and Vail were integral to parts of the design, manufacture, and sale of the Pinnacle System, and their promotion of the Pinnacle System was a necessary factor in bringing the product to the market and selling it to Plaintiff and his treating healthcare professionals. For example, Plaintiffs allege that on numerous occasions, Schmalzried and Vail met with orthopedic surgeons to promote the Pinnacle System Implant. At some or all of these meetings representatives of DePuy were present. During these meetings, Schmalzried and the DePuy representatives assured the orthopedic surgeons that the Pinnacle System was safe, was the best product on the market, had an excellent track record, and had a low and acceptable failure rate. Schmalzried and the DePuy representatives continued to defend

the Pinnacle System Implant even after they became aware of numerous and serious complications with the Pinnacle System. Schmalzried, Vail, and other of the DePuy representatives did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons.

57. Had Defendants conducted clinical trials of the Pinnacle System before it was first released on the market in the early 2000's, they would have discovered at that time what was ultimately learned in and around 2007 -that the Pinnacle System results in a high percentage of patients developing metallosis, biologic toxicity and an early and high failure rate due to the release of metal particles in the patient's surrounding tissue when the cobalt-chromium metal formal head rotates within the cobalt-chromium metal Acetabular liner. In other words, implantation of the Pinnacle System results in the nearly immediate systemic release of high levels of toxic metal cobalt-chromium ions into every hip implant patient's body. This is because cobalt-chromium metal particles are released by friction from the metal femoral head rotating within the metal liner. The particles than accumulate in the patient's tissue surrounding the implant giving rise to metallosis, pseudo tumors, or other conditions.

58. The formation of metallosis, pseudo tumors, and infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and a lack of mobility.

59. On information and belief, Plaintiff alleges that the FDA has received more than 1,300 adverse reports regarding

problems associated with or attributed to the Pinnacle System

60. Defendants continued to sell the Pinnacle System to doctors who implanted them in countless numbers of patients with an unreasonably high percentage of those patients being forced to endure serious injury from metallosis, pseudo tumors, and biologic toxicity, among other complications, and represent to the public that they are safe. These patients are reporting severe pain and discomfort and the need for one or more complicated revision surgeries resulting in life-long health problems caused by the defective System.

61. It also was not long after the defendants launched the Pinnacle System that defendants began receiving reports of failures. DePuy dismissed these complaints.

62. The defendants subsequently received a large number of similar complaints reporting that the Pinnacle System had failed due to premature loosening of the acetabular cup and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip implant component. Reports to the defendants that the Pinnacle System has failed continue to be made.

63. Plaintiffs allege that defendants had received numerous complaints related to the Pinnacle System and were fully aware that the Pinnacle System was defective and that patients already had been injured by that defect. Defendants should have recalled the Pinnacle System before plaintiff's implantation. At a minimum, the defendants should have stopped selling the defective implant when they became aware that it had catastrophically failed in several

patients.

64. Despite their knowledge that the Pinnacle System had a defect and that it had failed hundreds of times, causing numerous patients to undergo another surgery, the defendants continued to sell the defective hip implant. In so doing, the defendants actively concealed the known defect from doctors and patients - including plaintiff and her physicians - and misrepresented that the Pinnacle System was a safe and effective medical System.

65. Despite large numbers of failure reports of the Pinnacle implant, defendants, and DePuy and Schmalzried, continued to actively promote, market and defend the defective products. For example, Schmalzried authored many marketing brochures for DePuy touting the safety and durability of metal-on-metal implants and specifically, the Pinnacle System. These brochures containing Schmalzried's endorsements were given to doctors around the world to encourage them to use the Pinnacle System. Schmalzried made several false representations about the quality and safety of the Pinnacle System.

66. Despite knowledge that the Pinnacle System was defective, Schmalzried also made several false representations about specific design elements of the Pinnacle System that he claimed made it superior to other, safer, hip implants on the market.

67. The defendants' reason to conceal the defects in the ASR System and Pinnacle System was greed. DePuy is one of Johnson & Johnson's most profitable subsidiaries. The defendants were faced with a critical defect in two of their hip implant systems, but did not want to admit that these products contained defects that could

cause premature failure, forcing patients to undergo painful surgery. Focused on corporate profits, and at the expense of patient safety, each of the defendants decided that they would continue to promote, market, and sell the Pinnacle System despite the fact that they each knew the product was defective.

68. DePuy still has not recalled this product, but on information and belief defendant ceased selling this defective product to unsuspecting patients without any warning about the risks or the failures that have been reported to the company until sometime in 2013.

69. All Defendants designed, manufactured, marketed, and sold the Pinnacle MoM Device. The Pinnacle MoM Device was designed, developed, marketed, and sold for the purpose of replacing human hip joints damaged or diseased due to, inter alia, fracture, osteoarthritis, rheumatoid arthritis, and avascular necrosis with an artificial joint that would provide pain relief and consistent and smooth range of motion. Defendants marketed the Pinnacle MoM Device as having significant advantages over other hip devices and hip replacement systems. Defendants marketed and described the Pinnacle MoM Device as "[u]niquely designed to meet the demands of active patients like you - and help reduce pain" and advertised it with pictures of a young woman trying on sneakers in an athletic shoe store. Defendants advertised the Pinnacle MoM Devices as superior devices featuring "TrueGlide technology," allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion." Defendants also advertised and sold the Pinnacle MoM Device as the best

surgical option that "[r]ecreates the natural ball-and-socket joint of your hip, increasing stability and range of motion."

70. Defendants sold approximately 150,000 Pinnacle MoM Devices, each with the "Johnson & Johnson" logo on the package. In marketing and advertising the Pinnacle MoM Devices, Defendants made use of the "Johnson & Johnson" name and the familiarity of doctors and the public at large with Johnson & Johnson and its products. DePuy refers to itself as "a Johnson & Johnson Company" on letterhead and logos. When problems became apparent with DePuy's "ASR" hip implant, another metal-on-metal design, DePuy relied on its status as "a Johnson & Johnson Company" in an attempt to restore confidence among surgeons, and to encourage them to use the Pinnacle MoM Device in place of the ASR hip after it was recalled. All of these actions were taken with the knowledge, approval and encouragement of Johnson & Johnson. Johnson & Johnson directly participated in promotional and marketing efforts to promote the use of metal-on-metal hips in general, and the Pinnacle MoM Device in particular. Johnson & Johnson personnel approved specific marketing and promotional messages, approved Defendants' marketing of devices, including the Pinnacle MoM Device, and directly participated in "damage control" in the wake of the ASR recall, including efforts to convince surgeons that the Pinnacle MoM Device was still safe for use.

71. In addition, Johnson & Johnson specifically undertook to perform certain services for Defendants that it knew or should have known were necessary for the protection of patients implanted with Defendants' Pinnacle MoM Devices; Johnson &

Johnson failed to exercise reasonable care in performing those services; patients such as Plaintiff relied on Johnson & Johnson's performance and reputation; and Johnson & Johnson's performance of those services increased the risk of harm to patients, including Plaintiff.

72. Defendants have stated in promotional materials that "99.9% of Pinnacle hip components are still in use today." Plaintiffs have learned, however, that over 1,300 adverse reports have been submitted to the U.S. Food and Drug Administration ("FDA") regarding failures or complications of Pinnacle MoM Devices.

73. Despite their marketing of the Pinnacle MoM Device as a safe and superior device, Defendants were at all relevant times aware that implantation of Pinnacle MoM Devices may result in metallosis, biologic toxicity, and unreasonably high, early failure rates. Moreover, Defendants were aware at all times relevant to Plaintiffs' case that the Pinnacle MoM Device may result in unsafe release of toxic metal wear debris into hip implant recipients' tissue and bloodstream. At all relevant times, Defendants were aware that those metal particles from Pinnacle MoM Devices could cause metallosis, tissue death, bone erosion, the development of "pseudotumors," severe inflammation, severe pain, tissue and bone loss, and other related pathology. Defendants were also aware at all relevant times that Pinnacle MoM Device recipients often have elevated cobalt and chromium levels greatly exceeding acceptable safety standards.

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The Pinnacle MoM Device

74. The Pinnacle MoM Device was developed by Defendants for the purpose of reconstructing diseased human hip joints that had become damaged by conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), fracture, and other degenerative conditions. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

75. The Pinnacle MoM Device is made up of four components: the metal femoral stem, which is inserted inside the femur bone; the metal femoral head (or ball), which connects to the top of the stem; the metal acetabular cup or shell (socket), which attaches to the pelvis; and the liner, which sits inside the acetabular cup. The acetabular cup is made of titanium. The liner may be polyethylene (plastic), ceramic, or cobalt-chromium metal. The metal femoral head articulates within the liner. The Pinnacle MoM Device - the Pinnacle implant system when used with a metal liner -- is a "metal-on-metal" device because both articulating surfaces -- the femoral head (ball) and acetabular liner (socket) -- are comprised of cobalt-chromium metal.

Defendants Did Not Seek Premarket Approval from the FDA, and Thus the FDA Made No Finding That the Pinnacle MoM Device Is Safe or Effective

76. The Pinnacle MoM Device is a Class III medical device. Class III devices are those that operate to sustain human life, are

of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

77. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the Pinnacle MoM Device, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

78. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

79. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

80. A medical device on the market prior to the effective date of the MDA -- a so-called "grandfathered" device -- is not required to undergo premarket approval. In addition, a medical

device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976). This exception to the requirement of premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under § 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for marketing and sale in the United States.

81. Rather than being approved for use by the FDA pursuant to the rigorous premarket approval process, the Pinnacle metal-on-metal total hip replacement system was cleared by the FDA on the basis of Defendants' claim that, under § 510(k) of the MDA, it was "substantially equivalent" to another older metal-on-metal hip implant device that was sold and implanted prior to the enactment of the MDA in 1976.

82. Accordingly, under the 510(k) process, Defendants were able to market the Pinnacle MoM Device with virtually no clinical or non-clinical trials or FDA review of the implant for safety and effectiveness.

Defendants Did Not Adequately Test the Pinnacle MoM Device, and They Should Have Discovered That It Leads to Metallosis and Other Complications Before Releasing It into the Market

83. Defendants negligently failed to test the Pinnacle MoM Device adequately before releasing it into the market. Had

Defendants properly tested the Pinnacle MoM Device, they would have discovered the dangers of the device before bringing it to market.

84. Defendants knew or should have known that the Pinnacle MoM Device results in an unreasonably high percentage of patients developing metallosis, biologic toxicity, and an early and high failure rate due to the release of metal particles in the patient's surrounding tissue when the cobalt-chromium metal femoral head articulates against the cobalt-chromium metal acetabular liner and implant components corrode inside the body.

85. Implantation of the Pinnacle MoM Device results in the nearly immediate systemic release of high levels of toxic cobalt-chromium metal wear particles and metal ions into every hip implant patient's tissue and bloodstream. This is because cobalt-chromium metal particles are released by friction from the metal femoral head articulating within the metal liner, in addition to particles and ions being released by corrosion reactions. The particles and ions then accumulate in the patient's tissue surrounding the implant giving rise to metallosis, pseudotumors, infection, inflammation, and other adverse reactions.

86. The formation of metallosis, pseudotumors, infection, and inflammation causes severe pain and discomfort, death of surrounding tissue, bone loss, and lack of mobility.

87. FDA has received more than 1,300 adverse reports regarding problems associated with or attributed to the Pinnacle MoM Device.

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88. Many recipients of the Pinnacle MoM Device are suffering from elevated levels of chromium and cobalt. Plaintiff further alleges on information and belief that Defendants are aware that certain recipients of the Pinnacle MoM Device have significantly elevated levels or chromium and cobalt in amounts many times higher than acceptable or recommended safety levels.

89. A number of governmental regulatory agencies have recognized and cautioned against the problems that are caused by metal-on-metal implants such as the ASR and Pinnacle MoM Device. For instance, the United Kingdom's Medicines and Healthcare products Regulatory Agency ("MHRA") investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

90. The Alaska Department of Health issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

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Defendants Failed to Disclose and/or Warn About the Dangers of the Pinnacle MoM Device

91. Defendants failed to warn Plaintiff and/or his doctors, the medical community, and the public at large about the dangers of the Pinnacle MoM Device.

92. In particular, Defendants failed to warn that metal-on-metal implants, such as the Pinnacle MoM Device, could experience unusual, premature, or increased friction and/or wear and tear, and that such wear and tear could damage surrounding tissues and/or cause premature failure of the implant.

93. Defendants also failed to warn that metal-on-metal implants, such as the Pinnacle MoM Device, generated unusually high amounts of metal wear debris and metal ions over time due to the premature and/or increased friction and/or wear and tear of the device, and that this debris and ions can spread throughout the surrounding bone and tissue and cause serious complications and damage, including possible development of conditions commonly referred to in the medical community as ARMD (adverse reaction to metal debris), ALTR (adverse local tissue reaction), ALVAL (aseptic lymphocyte-dominated vasculitis-associated lesion), metallosis, and pseudotumors.

94. Defendants knew or should have known of each of the foregoing risks and dangers before releasing the Pinnacle MoM Device into the market and before the Pinnacle MoM Device was implanted into Plaintiff, but they failed to disclose them to, and concealed them from, Plaintiff and/or his doctors, the medical community, and the public at large.

95. In concealing, and failing to disclose, the risks and dangers of the Pinnacle MoM Device, Defendants' conduct was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, including Plaintiffs and the public at large.

96. Plaintiffs and their doctors were unaware of the risks and dangers of the Pinnacle MoM Device at the time the device was implanted.

97. Had the Defendants provided adequate warnings and information, Plaintiffs would not have undergone implantation with the dangerous and defective Pinnacle MoM Device.

Defendants Misrepresented the Benefits of the Pinnacle MoM Device

98. Defendants advertised the Pinnacle MoM Device as a superior device featuring "TrueGlide" technology, allowing the body to create a thin film of lubrication between surfaces, which enables "a more fluid range of natural motion."

99. This representation was false and/or misleading, and Defendants knew, or should have known, that it was false and/or misleading because Defendants knew, or should have known, that fluid film lubrication occurs rarely and is not present during the majority of movements of the Pinnacle MoM Device.

100. Defendants have stated in promotional materials that "99.9% of Pinnacle hip components are still in use today."

101. This representation was false and/or misleading, and Defendants knew, or should have known, that it was false and/or misleading. Defendants knew, or should have known, that the actual

survival rate of the device was substantially lower than they represented and that the data they cited support of the 99.9% statistic did not in fact support that representation.

102. Defendants marketed the Pinnacle MoM Device as especially suitable for younger and/or more active patients because of the claimed survivability rate of the device.

103. This representation was false and/or misleading, and Defendants knew, or should have known, that it was false and/or misleading. Defendants knew, or should have known, that the actual survival rate of the device was lower and knew, or should have known, that the data they cited in support of the 99.9% statistic did not in fact support that representation.

104. In 2013, the FDA announced it would no longer allow Defendants to market metal-on-metal hip implants, including the Pinnacle MoM Device, under the "grandfather"/510(k) method, and would instead require a Pre-market Application for any such devices. In response, Defendants announced they were discontinuing sales of the Pinnacle MoM Device in August of 2013.

105. In misrepresenting the benefits of the Pinnacle MoM Device to Plaintiff and to his physicians and to the public, Defendants' conduct was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, including Plaintiffs and the public at large.

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CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Negligence As To All Defendants

By Plaintiff Marile Aragon

106. Plaintiff Marile Aragon hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth in full.

107. Defendants had a duty to Plaintiff to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and distribution of the Pinnacle MoM Device into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer unreasonable, dangerous side effects, including those suffered by Plaintiff.

108. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and distribution of the Pinnacle MoM Device into interstate commerce. Defendants knew or should have known that those individuals that had the device surgically implanted were at risk of unreasonable, dangerous side effects, including those suffered by Plaintiff.

109. The negligence of Defendants included but was not limited to the following acts and/or omissions:

a. Designing the Pinnacle MoM Device in a manner which was not reasonably safe to those individuals who had the device surgically implanted;

b. Designing, manufacturing, producing, creating and promoting the Pinnacle MoM Device without adequately testing its safety;

c. Failing to conduct an adequate testing program to determine whether the Pinnacle MoM Device was safe;

d. Marketing and selling the Pinnacle MoM Device when Defendants knew or should have known that it was not reasonably safe and fit for use;

e. Selling the Pinnacle MoM Device without having conducted adequate testing to determine if the device was reasonably safe;

f. Failing to adequately and correctly warn Plaintiff and/or his physicians, the medical community, and the public at large of the dangers of the Pinnacle MoM Device;

g. Failing to recall their defective Pinnacle MoM Device at the earliest date that it became known that the device was, in fact, not reasonably safe;

h. Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably treat their patients with the Pinnacle MoM Device;

i. Advertising and recommending the use of the Pinnacle MoM Device despite the fact that Defendants knew or should have known that it is not reasonably safe;

j. Representing that the Pinnacle MoM Device was safe for use for its intended purpose, when, in fact, it was not reasonably safe;

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k. Representing that the Pinnacle MoM Device offered low wear and high stability, when, in fact, Defendants knew or should have known that neither statement was true;

l. Manufacturing the Pinnacle MoM Device in a manner that was not reasonably safe to those individuals who had it implanted;

m. Producing the Pinnacle MoM Device in a manner that was not reasonably safe to those individuals who had it implanted;

n. Assembling the Pinnacle MoM Device in a manner, that was not reasonably safe to those individuals who had it implanted; and

o. Under-reporting, underestimating, and downplaying the risks associated with of the Pinnacle MoM Device.

110. Defendants were further negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of the Pinnacle MoM Device in that they:

a. Failed to use due care in designing and manufacturing the Pinnacle Device so as to avoid unreasonable risks to individuals that had the devices surgically implanted;

b. Failed to accompany their product with adequate warnings;

c. Failed to accompany their product with adequate instructions for use;

d. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Pinnacle MoM Device; and

e. Were otherwise careless and negligent.

111. Despite the fact that Defendants knew or should have known that the Pinnacle MoM Device caused harm to individuals in whom the device was surgically implanted, Defendants continued to market, manufacture, distribute and sell the Pinnacle MoM Device to consumers, including Plaintiff.

112. Defendants knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury and be at increased risk of suffering an injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

113. Defendants' negligence was the proximate cause of Plaintiff's physical, mental, and emotional injuries and harm, and economic loss, which he has suffered and/or will continue to suffer.

114. As a direct and proximate result of Defendants' negligence, Plaintiff experienced and/or will experience severe personal injuries, including but not limited to partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future revisions, any and all life complications caused by Plaintiff's revision surgeries, as well as the need for lifelong medical treatment, monitoring and/or other medications. Plaintiff also needed a revision surgery to replace the device, and had to undergo the recovery therefrom, which caused him additional pain and suffering and carried the attendant risks of complications and death from such further surgery. Plaintiff also suffered a loss

of earnings as a result on Defendants' wrongdoing.

115. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, including the public at large, so as to justify an award of punitive damages.

116. By reason of the foregoing, Plaintiff Richard Canty demands judgment against each Defendant, individually, jointly and severally for compensatory damages in the amount of $2,000,000, and punitive damages in the amount of $5,000,000, together with costs of suit and all such other and further relief to which he may be entitled.

SECOND CLAIM FOR RELIEF

Strict Liability - Failure to Warn

As To All Defendants

By Plaintiff Marile Aragon

117. Plaintiff Marile Aragon hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth in full.

118. Defendants designed, manufactured, tested, marketed and distributed into the stream of commerce, and in the course of same, directly advertised or marketed the Pinnacle MoM Device to consumers or persons responsible for consumers, and therefore, had a duty to both Plaintiff directly and to his physicians to warn of risks associated with the use of Pinnacle MoM Device.

119. Defendants had a duty to warn of adverse effects which they knew or had reason to know could be caused by the use of the Pinnacle MoM Device and/or were associated with the use of the

Pinnacle MoM Device.

120. The Pinnacle MoM Device placed into the stream of commerce by Defendants and implanted in Plaintiff was defective because it was not accompanied by an adequate warning.

121. In particular, Defendants knew or should have known that the Pinnacle MoM Device was subject to early failure and could cause elevated blood levels of cobalt and/or chromium, metallosis, damage to surrounding tissues, and other complications. Defendants knew, or should have known, that such failure or complications in turn may give rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the device, with the attendant pain, suffering, and risks of complications and death from such further surgery. Defendants failed to give consumers and physicians adequate warning of such risks.

122. Defendants' failure to adequately warn Plaintiff and/or her treating physicians of the above risks prevented Plaintiff's treating physicians and Plaintiff from correctly and fully evaluating the risks and benefits of the Pinnacle MoM Device.

123. Had Plaintiff's physicians and Plaintiff been adequately warned of the serious side effects of the Pinnacle MoM Device, Plaintiff's physicians would have materially changed the information communicated to Plaintiff, including but not limited to, recommending a different device, or, even if they recommended the Pinnacle MoM Device, passing on the risks of that device to Plaintiff and discussing the risks with Plaintiff at the time of surgery and throughout the treatment of Plaintiff. Plaintiff would

not have consented to the implantation of the Pinnacle MoM Device had he been adequately informed of the risks of the Pinnacle MoM Device.

124. Due to the inadequate warning, the Pinnacle MoM device was in a defective condition and not reasonably safe at the time that it left the control of the Defendants.

125. The Pinnacle MoM Device placed into the stream of commerce by Defendants was surgically implanted in Plaintiff in a manner reasonably anticipated by Defendants.

126. As a foreseeable and proximate result of Defendants' placement of the defective Pinnacle MoM Device into the stream of commerce, Plaintiff experienced and/or will experience the injuries described above.

127. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, including the public at large, so as to justify an award of punitive and exemplary damages.

128. By reason of the foregoing, Plaintiff Richard Canty demands judgment against each Defendant, individually, jointly and severally for compensatory damages in the amount of $2,000,000, and punitive damages in the amount of $5,000,000, together with costs of suit and all such other and further relief to which he may be entitled.

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THIRD CLAIM FOR RELIEF

Strict Liability - Design Defect

As To All Defendants

By Plaintiff Marile Aragon

129. Plaintiff Marile Aragon hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth in full.

130. At the time it left Defendants hands, the Pinnacle MoM Device implanted in Plaintiff was defective because it was in a condition not reasonably contemplated by the ultimate consumer and was unreasonably dangerous for its intended use, and its utility did not outweigh the danger inherent in its introduction into the stream of commerce.

131. Defendants breached their duty to market safe products when they marketed a product designed so that it was not reasonably safe.

132. The defective design of Defendants' Pinnacle MoM Device was a substantial factor in causing Plaintiff' injuries described above.

133. Plaintiff's injury resulted when the defectively designed product was used for its intended purpose or for an unintended but reasonably foreseeable purpose.

134. At all times herein mentioned, the Pinnacle MoM Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

135. At all times material to these claims, there was a safer alternative design that was both technologically and economically feasible which would have prevented or substantially reduced the risk of Plaintiff's injuries without substantially impairing the device's utility.

136. At the time the Pinnacle MoM Device was implanted in him, Plaintiff was unaware of its defects, and Plaintiff could not, by the reasonable exercise of care, have discovered its defects.

137. Defendants are strictly liable to Plaintiff for the injuries she suffered due to the defective design of the Pinnacle MoM Device.

138. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, including the public at large, so as to justify an award of punitive damages.

139. By reason of the foregoing, Plaintiff Richard Canty demands judgment against each Defendant, individually, jointly and severally for compensatory damages in the amount of $2,000,000, and punitive damages in the amount of $5,000,000, together with costs of suit and all such other and further relief to which he may be entitled.

FOURTH CLAIM FOR RELIEF

Fraud and Fraudulent Concealment

As To All Defendants

By Plaintiff Marile Aragon

140. Plaintiff Marile Aragon hereby restates and re-alleges each and every allegation set forth above, with the same force and

effect as if herein repeated and set forth in full.

141. At the time Defendants manufactured, designed, marketed, sold and distributed the Pinnacle MoM Device, they had knowledge of the dangers metal-on-metal hip implant devices posed to their recipients. Further, Defendants had knowledge of the physical injury, pain and suffering, debilitation, and need for revision surgeries and subsequent complications that the Pinnacle MoM Device imposed on patients receiving the devices.

142. The dangers associated with the use of metal-on-metal devices, and the subsequent physical injury, pain and suffering, debilitation, and the need for revision surgeries and the subsequent complications were, and are, material facts.

143. Defendants knowingly, intentionally, and with reckless disregard of the true facts made material representations and material omissions and/or concealments to Plaintiff and/or his doctors, including, but not limited to, claims that the Pinnacle MoM Device was safe, effective, and fit for use as a hip replacement device.

144. Defendants' misrepresentation and omission of known facts were intended to induce Plaintiff and/or his doctors to purchase and use the Pinnacle MoM Device.

145. Defendants knew or should have known that their representations were false or misleading and/or knew that Defendants were concealing and/or omitting material information from the medical and healthcare community at large, the general public, Plaintiff's healthcare providers, and/or Plaintiff.

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146. Plaintiff and/or his doctors relied on Defendants' misrepresentations of material facts regarding the safety, effectiveness and fitness of the Pinnacle MoM Device for use as a hip replacement device. Plaintiff and/or his doctors further relied on Defendants to provide them with information about the dangers of the Pinnacle MoM Device, and not to conceal information they had about such dangers. Had Plaintiff known the risks associated with the use of the Pinnacle MoM Device, he would not have consented to the Pinnacle MoM Device being permanently implanted in his body.

147. Plaintiff and/or his doctors justifiably relied on the information provided by Defendants in deciding whether to obtain, implant, and retain the Pinnacle MoM Device.

148. As a direct and proximate result of reliance on the Defendants' misrepresentations, Plaintiff has suffered and will suffer the injuries described above.

149. Defendants' conduct as described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, including the public at large, so as to justify an award of punitive damages.

150. By reason of the foregoing, Plaintiff Richard Canty demands judgment against each Defendant, individually, jointly and severally for compensatory damages in the amount of $2,000,000, and punitive damages in the amount of $5,000,000, together with costs of suit and all such other and further relief to which he may be entitled.

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FIFTH CLAIM FOR RELIEF

Negligent Misrepresentation

As To All Defendants

By Plaintiff Marile Aragon

151. Plaintiff Marile Aragon hereby restates and re-alleges each and every allegation set forth above, with the same force and effect as if herein repeated and set forth in full.

152. Defendants made misrepresentations of material facts in the course of their business, including, but not limited to:

a. That Plaintiff's Pinnacle MoM implant was fit for its intended use;

b. That Plaintiff's Pinnacle MoM implant was of merchantable quality;

c. That Plaintiff's Pinnacle MoM implant was safe and effective in the treatment of Plaintiff's medical condition; and,

d. That Plaintiff's Pinnacle MoM implant would function as intended when necessary.

153. Defendants omitted to reveal material facts, including, but not limited to:

a. That Plaintiff's Pinnacle MoM implant was defective, such that it would fail to function as intended;

b. That Plaintiff's Pinnacle MoM implant presented a risk of injury and harm in its ordinary and intended use; and

c. That Plaintiff's Pinnacle MoM implant was not reasonably safe.

154. These representations and/or omissions were false and misleading at the time they were made.

155. False information about the characteristics and safety of the Pinnacle MoM implant was supplied by Defendants for the guidance of others.

156. Defendants did not exercise reasonable care or competence in obtaining or communicating this information, but rather negligently and carelessly made the foregoing misrepresentations.

157. When Defendants made the foregoing representations, they intended to induce Plaintiff and/or his doctors to select the Pinnacle MoM Device for use in Plaintiff's hip replacement surgery.

158. The relationship between the Defendants and the Plaintiff was, in essence, a fiduciary relationship. The Defendants held themselves out to Plaintiff and to the public as having the highest level of medical and scientific knowledge and expertise, and that they could be trusted to provide an artificial joint part that he could safely incorporate as a part of his body and rely on for years to come. In other words, the foundation of Defendants' marketing of the Pinnacle MoM Device approach was Defendants' assurances, express or implied, was that Plaintiff could trust them and that product to provide physical health benefit to him for many years to come.

159. In reliance upon the foregoing misrepresentations by the Defendants, Plaintiff was induced to and did subject herself to the use of the Pinnacle MoM Device. If Plaintiff had known of the true facts, he would not have taken such action and risk. Plaintiff's reliance on Defendants' misrepresentations and omissions was justifiable because said representations were made by individuals and entities in a position to know the true facts and who held

themselves out as possessing the highest medical and scientific expertise.

160. As a direct and proximate result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered the injuries herein described.

161. Defendants' conduct as described herein was so grossly negligent as to indicate a wanton disregard of the rights of others, including the public at large, so as to justify an award of punitive damages.

162. By reason of the foregoing, Plaintiff Richard Canty demands judgment against each Defendant, individually, jointly and severally for compensatory damages in the amount of $2,000,000, and punitive damages in the amount of $5,000,000, together with costs of suit and all such other and further relief to which he may be entitled.

SIXTH CLAIM FOR RELIEF

Breach of Implied Warranty of Merchantability

As To All Defendants

By Plaintiff Marile Aragon

163. Plaintiff Marile Aragon restates and re-alleges each and every allegation set forth above with the same force and effects as it set forth herein and repeated in full.

164. Defendants are in the business of designing, manufacturing, and/or supplying and/or placing into the stream of commerce the Pinnacle MoM Device for consumers.

165. By placing the Pinnacle MoM Device into the stream of commerce, Defendants impliedly warranted that it was merchantable

and fit for the ordinary purpose for which it was intended.

166. The Pinnacle MoM Device placed into the stream of commerce by Defendants was defective and, accordingly, was not merchantable or fit for the ordinary purpose for which it was intended.

167. The defects in the Pinnacle MoM Device designed, manufactured and/or supplied and/or placed into the stream of commerce by Defendants, were present at the time the product left Defendants' control.

168. Defendants breached the implied warranty for the Pinnacle MoM Device.

169. Plaintiff was a foreseeable user of the Pinnacle MoM Device designed, manufactured and/or supplied and placed into the stream of commerce by Defendants.

170. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff suffered, and will continue to suffer the injuries previously described, rendering Defendants liable for said damages.

171. Defendants' conduct described herein was fraudulent, malicious, oppressive, willful, and/or so grossly negligent as to indicate a wanton disregard of the rights of others, including the public at large, so as to justify an award of punitive damages.

172. By reason of the foregoing, Plaintiff Marile Aragon demands judgment against each Defendant, individually, jointly and severally for compensatory damages in the amount of $2,000,000, and punitive damages in the amount of $5,000,000, together with costs of suit and all such other and further relief to which he may be

entitled.

SEVENTH CLAIM FOR RELIEF

Loss of Consortium

As To All Defendants

By Plaintiff Rodney Aragon

173. Plaintiffs Marile Aragon and Rodney Aragon restate and re-allege each and every allegation set forth above with the same force and effects as it set forth herein and repeated in full and further allege as follows.

174. Plaintiff RODNEY ARAGON at all times relevant is and was the long-time lawfully wedded Spouse of Plaintiff MARILE ARAGON.

175. As a direct, legal and proximate result of the culpability and fault of the defendants, plaintiff RODNEY ARAGON suffered the loss of support, service, love, companionship, affection, society, intimate relations, and other elements of consortium, all to plaintiffs' general damage, in an amount in excess of the jurisdictional minimum of this Court.

176. By reason of the foregoing, Plaintiff Rodney Aragon demands judgment against each Defendant, individually, jointly and severally for compensatory damages in the amount of $2,000,000, together with costs of suit and all such other and further relief to which he may be entitled.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, Marile Aragon and Rodney Aragon, demand judgment against all named Defendants, on each of the above-referenced claims as follows:

A. Awarding compensatory damages to Plaintiffs for past and future damages including but not limited to past and future medical expenses, past and future loss of earnings, disfigurement, pain and suffering, mental anguish and emotional distress, in such amounts as may be proven at trial, together with interest and costs as provided by law;

B. Awarding punitive damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

C. Awarding Plaintiffs the costs of these proceedings; and

D. Awarding such other and further relief as this Court deems just and proper.

DATED: October 31, 2022

CHAMBERS & NORONHA

By: _____
GARY L. CHAMBERS
GARRETT R. CHAMBERS
Attorneys for Plaintiffs
MARILE ARAGON and
RODNEY ARAGON

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DEMAND FOR JURY TRIAL

Plaintiffs MARILE ARAGON and RODNEY ARAGON hereby demand trial by jury on all claims for relief properly triable by jury.

DATED: October 31, 2022

CHAMBERS & NORONHA

By: _____
GARY L. CHAMBERS
GARRETT R. CHAMBERS
Attorneys for Plaintiffs
MARILE ARAGON and
RODNEY ARAGON

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PROOF OF SERVICE

I am employed in the County of Orange, State of California; I am over the age of 18 and not a party to the within action; my business address is 2070 North Tustin, Santa Ana, CA 92705-7827.

On **November 2, 2022**, I served the foregoing; **FIRST AMENDED COMPLAINT FOR DAMAGES**; on the interested parties as follows:

By Mail: By placing true copies thereof enclosed in sealed envelope(s) with postage thereon fully prepaid, in the United States mail at Santa Ana, California as follows:

By Overnight Delivery: I caused such envelope(s) to be delivered via "next day" delivery to the following addressee(s):

By Facsimile: By causing said documents to be transmitted by Facsimile machine to the number indicated after the address(es) set forth below:

By Personal Service: I caused such envelope(s) to be delivered by hand to the following addressee(s):

XX ONLY BY ELECTRONIC TRANSMISSION: Only by e-mailing the document(s) to the persons at the e-mail address(es) listed based on notice provided on March 18, 2020 that, during the Coronavirus (Covid-19) pandemic, this office will be working remotely, not able to send physical mail as usual, and is therefore using only electronic mails. No electronic message or other indication that the transmission was unsuccessful was received within a reasonable time after the transmission.

PLEASE SEE ATTACHED SERVICE LIST

I am "readily familiar" with the firm's practice of collection and processing correspondence for mailing. Under that practice it would be deposited with the United States postal service on that same day with postage thereon fully prepaid at Santa Ana, California in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct. Executed on **November 2, 2022** at Santa Ana, California.

Chris Williams

SERVICE LIST

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